



**UNITED STATES DEPARTMENT OF COMMERCE**  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/444,335	11/19/99	ENIKOLOPOV	CSHL99-05

HM12/0803  
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EXAMINER  
SCHNIZER, R

ART UNIT	PAPER NUMBER
1632	9

DATE MAILED: 08/03/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Office Action Summary**

Application No.

09/444,335

Applicant(s)

Enikolopov et al

Examiner

Richard Schnizer

Group Art Unit

1632


☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claim**

- ☒ Claim(s) 1-50 is/are pending in the application
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claims 1-50 are subject to restriction or election requirement.

**Application Papers**

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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## **DETAILED ACTION**

### ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, 17, and 22-24, drawn to a transgenic animal, classified in class 800, subclass 8.
- II. Claims 9-16, drawn to a method of making a transgenic animal, classified in class 800, subclass 25.
- III. Claim 18, drawn to an expression construct, classified in class 536, subclass 23.5.
- IV. Claims 19-21, drawn to a method of measuring a cell population, classified in class 424, subclass 9.6.
- V. Claims 25-36, drawn to a method of obtaining cells, classified in class 435, subclass 30.
- VI. Claims 37-42 and 47, drawn to a method of screening compounds for promoting differentiation of stem cells, classified in class 435, subclass 7.21.
- VII. Claims 43-46 and 48-50, drawn to a method of assessing a compound's toxicity to stem cells, classified in class 435, subclass 7.21.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be

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used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the animal can be made by a different process wherein embryonic stem cells are transfected, selected for stable integration of the expression construct, and the resulting stem cells are inserted into a blastocyst, transplanted into a female, and allowed to develop to term.

The animal of group I is related to the construct of group III because the construct could be used in the process of making the animal. The inventions are distinct because the animal may be made using a different construct which comprises a nestin promoter rather than sequence from the second intron of the nestin gene. Alternatively, the construct of group III could be used to transfect primary neuronal cells *in vitro* in order to assess their status with respect to differentiation.

The construct of group III is related to the method of group II, because the construct could be used in the method. The inventions are distinct because the construct could be used for other purposes such as to transfect primary neuronal cells *in vitro* in order to assess their status with respect to differentiation.

The methods of groups IV-VII are distinct because they involve different steps, and provide different results. The method of group IV is directed to identifying and measuring cells. It requires no isolation steps as in the method of group V, and no testing steps as in the methods of groups VI and VII. The method of group IV allows one to follow the process of differentiation *in vivo*, and is therefore distinct. The method of group V is directed to obtaining

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cells. It requires no testing steps, and allows the obtained cells to be used for any purpose including either of the methods of groups VI and VII. The methods of groups VI and VII recite are directed to separate and distinct purposes which the measurement of different endpoints. Thus these methods are distinct.

The animal of group I is related to each of the methods of Groups IV-VII as a product and a process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case because the animal can be used in each of the distinct processes.

The method of group II is related to the methods of groups IV-VII because it can be used to generate the animal used in these methods. The inventions are distinct because the animal can be made by another distinct method such as transfection of an embryonic stem cell, selection for stable integration of the expression construct, insertion of the resulting stem cells into a blastocyst, transplantation into a female, and development to term.

The construct of group III is related to the methods of groups IV-VII because it can be used to generate the animal used in these methods. The inventions are distinct because the construct can be used for other purposes such as transfection of primary neuronal cells *in vitro* in order to assess their status with respect to differentiation.

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Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

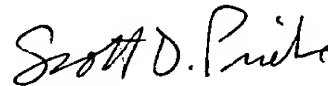
Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached on Mondays and Thursdays between the hours of 6:20 AM and 3:50 PM, and on Tuesdays, Wednesdays and Fridays between the hours of 7:00 AM and 4:30 PM (Eastern time). The examiner is off every other Friday, but is usually in the office anyway.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Stanton, can be reached at 703-308-2801. The FAX phone numbers for art unit 1632 are 703-308-4242 and 703-305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

Richard Schnizer, Ph. D.

A handwritten signature in black ink that reads "Scott D. Pribe". The signature is written in a cursive, flowing style.

**SCOTT D. PRIEBE, PH.D**  
**PRIMARY EXAMINER**